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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,364	09/21/2006	Peter Richard Smith	884B.0001.U1(US)	1225
29683 7590 01/23/2009 HARRINGTON & SMITH, PC 4 RESEARCH DRIVE, Suite 202 SHELTON, CT 06484-6212			EXAMINER WON, BRIAN D	
			ART UNIT 4185	PAPER NUMBER
			MAIL DATE 01/23/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/553,364	Applicant(s) SMITH ET AL.	
	Examiner BRIAN WON	Art Unit 4185	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 55-73 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 55-73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 October 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :14 October 2005 and 21 September 2006.

DETAILED ACTION***Specification***

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 55-73** are rejected under 35 U.S.C. 102(b) as being anticipated by **Shofner et al. (US 2003/0016357 A1)**.

Regarding claim 55, Shofner et al. discloses a method comprising the steps of:

- a) providing a drug (208) into an air flow past a sensor comprising a radiation source (200) and a radiation detector (230) ([0046]);
- b) detecting, at the radiation detector, incident radiation over a period of time as a measurement profile ([0056]);
- c) quantifying at least one characteristic (mass concentration, volume flow rate or mass flow rate) of the shape of a measurement profile ([0052] results are sent to (400)) ; and
- d) producing an indication of the effectiveness (ratio) of pulmonary drug delivery based upon the at least one quantified characteristic ([0057], lines 18-21).

Regarding claim 56, Shofner et al. discloses a method wherein the indication of the effectiveness of pulmonary drug delivery quantifies the amount of fine particles in the delivered pulmonary drug ([0005]).

Regarding claim 57, Shofner et al. discloses a method wherein the at least one characteristic is a height (mass flow rate) of the measurement profile ([0010], lines 1-3).

Regarding claims 58 and 59, Shofner et al. discloses a method wherein the at least one characteristic involves an integration of the measurement profile over its width ([0029] and [0037]).

Regarding claims 60 and 61, Shofner et al. discloses a method wherein the curve fitted to the measurement profile is a dose function which when summed with a level transition residual function substantially re-creates the measurement profile ([0029]).

Regarding claim 62, Shofner et al. discloses a device ([0054]) comprising:

- a conduit (10) through which air carrying a cloud of drug particles can flow during drug delivery;
- a radiation source (210) for providing radiation into the conduit;
- a radiation detector (212) for detecting radiation from the conduit over a period of time as a measurement profile; and
- a processor (400) operable to quantify one or more characteristics of the shape of a measurement profile and to produce an indication of the effectiveness of pulmonary drug delivery based upon the quantified characteristic(s) ([0052] and [0057], lines 18-21).

Regarding claim 63, Shofner et al. discloses a device arranged for releasable attachment to a drug dispensing device ([0009], lines 4-6).

Regarding claim 64, Shofner et al. discloses a device wherein the indication of the effectiveness of pulmonary drug delivery indicates the fine particle component of the delivered pulmonary drug ([0005]).

Regarding claim 65, Shofner et al. disclose a quantified characteristic is the height (mass flow rate) of the measurement profile ([0010], lines 1-3).

Regarding claim 66 and 67, Shofner et al. discloses a quantified characteristic involves the integration of the measurement profile over its width ([0029] and [0037]).

Regarding claim 68, Shofner et al. discloses a device comprising a second radiation detector for detecting radiation from the conduit over a period of time as a second measurement profile (see claim 7), wherein the processor (400) is operable to produce an indication of the effectiveness of pulmonary drug delivery based upon a plurality of measurement profiles for a single drug delivery ([0052] and [0057], lines 18-21)..

Regarding claim 69, Shofner et al. discloses a second radiation source (see claim 7).

Regarding claim 70, Shofner et al. discloses a method comprising the steps of:

- recording (since the multiple results are sent to CCM (400) at various time, it can be considered recording), during a drug delivery, the output of a first radiation detector against time as a first measurement profile (see claim 1);

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- recording, during the same drug delivery, the output of a second radiation detector against time as a second measurement profile (see claim 1 and 7);and
- processing the first and second measurement profiles to produce an indication of the effectiveness of pulmonary drug delivery ([0052] and ([0057], lines 18-21).

Regarding claim 71, Shofner et al. discloses a device (see claim 31)

comprising:

- a conduit (10) through which air carrying a cloud of drug particles can flow during drug delivery;
- a radiation source (first sensor where sensors comprises a radiation source) for providing radiation into the conduit;
- a first radiation detector (first sensor where sensors comprises a radiation detector) for detecting radiation from the conduit over a period of time as a first measurement profile;
- a second radiation detector (second sensor) for detecting radiation from the conduit over the period of time as a second measurement profile; and
- a processor (400) operable to produce an indication of the effectiveness of pulmonary drug delivery based upon the first and second measurement profiles.

Regarding claim 72, Shofner et al. discloses a device comprising:

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- a drug metering means for releasing a controlled amount of drug for each drug delivery (according to abstract, controlling deliveries of aerosols) ;
- a conduit (10) through which air carrying a cloud of drug particles can flow;
- a radiation source (210) for providing radiation into the conduit;
- a first radiation detector (212) for detecting radiation from the conduit during a on-going drug delivery as a first measurement profile; and
- control means (400) operable to control the drug metering means, for a subsequent drug delivery, in dependence upon at least the first measurement profile.

Regarding claim 73, Shofner et al. discloses drug metering means (controlled delivery of aerosol) is arranged to vary the amount of drug released in a subsequent drug delivery, in dependence upon at least the first measurement profile or is arranged to vary the number of drug deliveries required in dependence upon at least the first measurement profile (Abstract and [0038]).

Conclusion

3. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following reference are cited for disclosing related limitations of the applicant's claimed and disclosed invention: **Shofner et al. (US 2003/0016357 A1)**.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRIAN WON whose telephone number is

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(571)270-7129. The examiner can normally be reached on Monday thru Friday, 9:00 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrell McKinnon can be reached on (571)272-4797. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BRIAN WON/
Examiner, Art Unit 4185

/Terrell L McKinnon/
Supervisory Patent Examiner, Art Unit 4185